Versar inc.

M E M O R A N D U M

TO: Laura Casey cc: Jim Buchert
11.1126.1000.001.01

FROM: Diane Sinkowski

DATE: January 23, 2005

SUBJECT: Review of "Exposure and Screening-level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214"(December 6, 2004)

I have the reviewed the submitted risk assessment and have provided, below, comments addressing the items specified by EPA in the technical direction provided by Region 1 on 12/20/04.

1. Does the *Exposure Assessment* consider all pathways for the uses included in the assessment? If not, please provide comments and/or recommendations. Please include Versar's justifications using appropriate EPA procedures and guidance.

   The pathways considered seem appropriate for the exposure scenarios evaluated.

2. Were Versar's October 25, 2004 comments adequately addressed in the *Exposure Assessment?* If not, please provide comments and/or recommendations. Please include Versar's justifications using appropriate EPA procedures and guidance.

   Versar's previous comments have been adequately addressed.

3. Are there areas where data gaps exist and where additional information is required? Versar shall identify any data deficiencies, and if found, provide possible resolutions such as (but not limited to) the collection of additional samples or requesting additional information.

- On page 2-5, the risk assessment indicates that a soil dust ingestion rate of 55 mg per day was assumed for children and is based on data from Moya et al. (2004). I was unable to find this value in the cited reference. The Moya et al. reference states the following:

  Children's mean soil ingestion values ranged from 39 mg/day to 271 mg/day with an average of 138 mg/day for soil ingestion and 193 mg/day for soil and dust ingestion. Upper percentile values average 358 mg/day for soil and 790 mg/day for soil and dust combined.

Could Clariant please provide clarification on the origin of the assumed value?

- Clariant should provide information regarding exposure frequency and duration for the food wrap scenario and revise the calculations shown at the bottom of page 3-2 accordingly, since the calculations only reflect one day's consumption of cheese. In particular, for carcinogenic risk, the calculated daily dose shown, 0.0000014 mg tPCBs/kg BW/day, cannot be compared to the target lifetime average daily dose of 0.000014 mg/kg BW/day (Table 1) without dividing by the lifetime averaging time (i.e., 25,550 days).

- Table 1 (page 7-1) of the risk assessment indicates that a slope factor of 0.07 $(mg/kg\text{-}d)^{-1}$ was assumed for calculating the cancer risk from ingestion, dermal absorption, and inhalation of PCBs. The value is the upper-bound slope factor for PCBs of the lowest risk and persistence. EPA's criteria for use of this slope factor (www.epa.gov/iris/subst/0294.htm) is that congener or isomer analyses verify that congeners with more than 4 chlorines comprise less than 1/2% (0.5%) of total PCBs. Page 1-2 (bottom paragraph) of the risk assessment indicates that PCB congeners 44 and 70 make up approximately 90 percent of the total PCBs found in Pigment Red 144 and 214. It is uncertain from this statement whether the additional PCB congeners in the pigments are of low chlorine content. Clariant should demonstrate to EPA that the composition of the pigments meets EPA's criteria for use of the 0.07 $(mg/kg\text{-}d)^{-1}$ slope factor.

4. Are the formulas provided in the *Exposure Assessment* appropriate and are the proposed exposure/risk model input parameters correct? If not, please provide comments and/or recommendations using appropriate EPA procedures and guidance.

- According to the risk assessment, Equation 4 (page 2-3) is obtained by substituting Equation 3 into Equation 2 (both on page 2-2), and solving for C_g (room air concentration of tPCB vapor). Equation 4 (without the parameter "D") is as follows:

$$C_g = \left(\frac{d_w \times 10^{3.83-0.62 \times \log VP}}{M} \right)$$

However, as shown in the steps below, the substitution has not been performed correctly:

$$\text{Given: } K_{SA} = \frac{\frac{k_s}{k_d}}{d_w} = 10^{3.82 - 0.62 \times \log VP}$$

and

$$K_{eq} = \frac{k_s}{k_d} = \frac{M}{C_g}$$

Substituting for $\frac{k_s}{k_d}$:

$$K_{SA} = \frac{\frac{M}{C_g}}{d_w} = 10^{3.82 - 0.62 \times \log VP}$$

Rearranging to solve for C_g:

$$C_g = \frac{\frac{M}{10^{3.82 - 0.62 \times \log VP}}}{d_w} = \frac{M}{d_w \times 10^{3.82 - 0.62 \times \log VP}}$$

This correction should be made and any calculations performed using this equation should be revised.

- The parameter M, as defined in the risk assessment, is incorrect. Table 1 (page 7-1) of the risk assessment indicates that M is the carpet area mass (face weight; mg/m^2). The parameter M, as defined in the Bennett and Furtaw (2004) and the Won, et al. (2000) papers, is the mass of the compound [PCBs] collected on the sink [carpeting] per unit area (mg/m^2). Therefore, the value shown in Table 1 for the carpet area mass and the calculated air concentration in an enclosed space 7 days post installation of a new carpet are incorrect, unless Clariant means to assume that the entire mass of the carpet is tPCBs.
- Equation 5 from the risk assessment (see below), has parameters representing the tPCB concentration in the carpeting (CC_{Carpet}) and the concentration in the air (C_g). There cannot be two concentration parameters in the equation. When a unit analysis is done, one can see that the ingestion and dermal absorption parameters cancel to mg/kg as they should, since the equation is being solved for CC_{Carpet} which is in units of mg/kg. However, when the units for the inhalation contribution to the equation are canceled, the term is unitless instead of being mg/kg. Equation 5 and the calculations for CC_{Carpet} should be revised.

$$CC_{carpet} = \frac{TR \times BW \times AT_c}{ED \times EF \times \left[\left(\frac{CSF \times IR \times BioAF}{10^6\ mg/kg}\right) + \left(\frac{CSF \times SA \times AF \times DERM}{10^6\ mg/kg}\right) + \left(CSF \times IHR \times C_g \times VRF\right)\right]}$$

$$CC_{carpet}\ (\text{inhalation term only})\left(\frac{mg}{kg}\right) = \frac{TR \times BW \times AT_c}{ED \times EF \times \left(CSF \times IHR \times C_g \times VRF\right)} = \frac{(-) \times (kg) \times (days)}{(yr) \times \left(\frac{days}{yr}\right) \times \left(\frac{mg}{kg-day}\right)^{-1} \times \left(\frac{m^3}{day}\right) \times \left(\frac{mg}{m^3}\right) \times (-)} = (-)$$

- A volatilization rate factor, VRF, is included in the inhalation exposure calculation. However, since the equation from the Bennett and Furtaw (2004) paper, already takes into account desorption of the compound (tPCBs) from the sink material (carpeting), a VRF should not be included in the calculation if the methodology from the Bennet and Furtaw paper is to be used to calculate a tPCB air concentration.

- A bioavailability factor, (assumed values were 1, 5, 10, 50, and 100%, see Table 1), was included in the calculation of the ingestion dose. Although EPA has studied and provided some guidance regarding the relative bioavailability of metals, such as lead, at this time, U.S. EPA has not provided guidance for PCBs. Until EPA reviews all the studies on PCBs and comes to a consensus regarding the relative bioavailability of PCBs in soil, no bioavailability factors should be included when calculating PCB intakes via the ingestion pathway.

Please contact me if there are any questions regarding these comments or if additional information is needed.